REMARKS

An interview was conducted between the Examiner, Summer L. Kostelnik; the undersigned, Alan E. Schiavelli; and Giles N. Turner on December 28, 2010. During the interview, the proposed amendments to Claim 9 were discussed, and the rejections of Claim 9 under the provisions of 35 U.S.C. §112, second paragraph were reviewed in light of the proposed amendments. The Examiner noted that the recitations of Claim 9 were more clearly defined. In addition, the rejection of Claim 9 under the provisions of 35 U.S.C. §103(a) in light of the disclosures of DiGioia et al. and Ferrante et al. was discussed during the interview. The Examiner suggested that the undersigned submit, in writing, the amendments and arguments traversing the rejections set forth in the Office Action mailed October 10, 2010, for further consideration.

Applicants note the Examiner has withdrawn Claims 1-8 in response to the Applicants election of Group II, including Claim 9, drawn to a total knee joint replacement terminal, on July 22, 2010.

Applicants have amended their Claims in order to further clarify the definition of various aspects of the present invention. Specifically, Applicants have amended Claim 9 to recite "[a] total knee joint replacing operation assisting terminal, constituted by a computer configured to assist a total knee joint replacing operation by performing a planning assistance function and an intraoperative assistance function; wherein the planning assistance function is used before an intervention on a patient, and the intraoperative assistance function is used during the intervention on a patient, whereby the terminal is configured to assist the total knee joint replacing operation performed with aid of a bone cutting positioning jig indicating a bone cutting direction by the intraoperative assistance function; wherein the bone

cutting positioning jig comprises a bone cutting direction indicator having a base, a universal joint being movably and rotatably supported around three axes to the base of the bone cutting direction indicator through a ball joint and having a direction indicating jig, and an intra-medullary rod fixed to one end of the universal joint; wherein the intra-medullary rod comprises, a cylindrical body made of an X-ray transmitting material fixed at a central portion between a pair of both ends of the intra-medullary rod, a plurality of wires, which are made of a material that does not transmit X-ray and are deposited at regular intervals along a surface of the cylindrical body in the circumferential direction, being extended in an axial direction in a spiral shape; wherein an intersection of each of the wires having a marker indicator function providing rotational position information; wherein each of the wires is made in a way that a starting end and a terminating end of the cylindrical body are connected by the shortest distance along the outer surface thereof; wherein the planning assistance function includes: acquiring a load shaft of a patient's foot from 3-dimensional radiographic image data, and storing computer model data, on the intra-medullary rod to be inserted into a medullary cavity, in a database; wherein the intraoperative assistance function includes: acquiring, from the database, the computer model data on the intra-medullary rod to be inserted; reading the computer model data, acquired from the database, on the intra-medullary rod to be inserted; acquiring, by a C-arm fluoroscopic apparatus, radiographic image data of the intra-medullary rod inserted into a tibia of the patient; acquiring, on the radiographic image data obtained by the fluoroscopic apparatus, rotational position information of the intra-medullary rod in a medullary cavity of the patient based on the position of the intersection of the pair of wires of the intra-medullary rod; and determining a resected bone surface using the intra-medullary rod as a reference anatomical axis;

and wherein an anterior articular surface of the femur is determined perpendicularly to the load shaft of the patient from an angle with the femoral load shaft determined using the planning assistance function before the intervention, and a bone surface to be resected is determined." For example, support for the current amendment to Claim 9 may be found in the Specification at page 1, lines 9-11; page 6, lines 16-25; page 7, lines 17-22; page 9, line 23 through page 10, line 15; page 14, line 15 through page 17, line 15; page 17, line 23 through page 23, line 4; page 28, line 2 through page 34, line 3; and Figs. 1B, 2A-2F, 7, and 9.

Applicants have added new Claim 10, which recites "[t]he total knee joint replacing operation assisting terminal of claim 9, wherein the planning assistance function further includes performing a 3-dimensional simulation for mounting an artificial knee implant based on the 3-dimensional radiographic image data." For example, support for new Claim 10 may be found in the Specification at page 16, lines 7-15; and page 29, line 16 through page 31, line 1; and Fig. 7.

Applicants have added new Claim 11, which recites "[t]he total knee joint replacing operation assisting terminal of claim 10, wherein the planning assistance function further includes determining a kind of artificial knee implant to be used." For example, support for new Claim 11 may be found in the Specification at page 29, line 16 through page 31, line 1; and Fig. 7.

Applicants have added new Claim 12, which recites "[t]he total knee joint replacing operation assisting terminal of claim 11, wherein the planning assistance function further includes determining a setting position of the artificial knee implant." For example, support for new Claim 12 may be found in the Specification at page 29, line 16 through page 31, line 1; and Fig. 7.

Applicants have added new Claim 13, which recites "[t]he total knee joint replacing operation assisting terminal of claim 12, wherein the planning assistance function further includes superposing the 3-dimensional radiographic image data with the setting position of the artificial knee implant." For example, support for new Claim 13 may be found in the Specification at page 29, line 16 through page 30, line 2; and Fig. 7

Applicants have added new Claim 14, which recites "[t]he total knee joint replacing operation assisting terminal of claim 9, wherein the intraoperative assistance function further includes superposing the computer model data on the intra-medullary rod to be inserted on the radiographic image data acquired during the intraoperative assistance function." For example, support for new Claim 14 may be found in the Specification at page 32, lines 12-20; and Fig. 9.

Applicants have added new Claim 15, which recites "[t]he total knee joint replacing operation assisting terminal of claim 9, wherein the intraoperative assistance function further includes resecting a bone surface using the bone cutting positioning jig and the determined resected bone surface." For example, support for new Claim 15 may be found in the Specification at page 30, line 3 through page 34, line 3; and Fig. 9.

Applicants have added new Claim 16, which recites "[t]he total knee joint replacing operation assisting terminal of claim 9, wherein the radiographic image data is a fluoroscopic image." For example, support for new Claim 16 may be found in the Specification at page 9, lines 12-13.

In response to the objection to the drawings set forth on page 2 of the Office Action mailed October 8, 2010, Applicants have submitted replacement sheets 1-15 containing FIGs. 1A-12B in the English language. In view of the current amendment

to the drawings, Applicants respectfully submit that the above-noted objection to the drawings is moot. Applicants respectfully submit that the replacement sheets 1-15 and current amendment to FIGs. 1A-12B do not add new matter.

Applicants respectfully submit that the rejection of Claim 9 under the provisions of 35 U.S.C. §112, second paragraph, the Examiner contending that it is unclear whether the computer has a planning assistance function and an intraoperative function or the assisting terminal, is moot in light of the current amendment of Claim 9 to recite, inter alia, "[a] total knee joint replacing operation assisting terminal, constituted by a computer configured to assist a total knee joint replacing operation by performing a planning assistance function and an intraoperative assistance function." Applicants respectfully submit that the rejection of Claim 9 under the provisions of 35 U.S.C. §112, second paragraph, the Examiner contending that it is also unclear what is meant by "supports a total knee joint replacement," is moot in light of the current amendment of Claim 9 to recite, inter alia, "whereby the terminal is configured to assist the total knee joint replacing operation." Applicants respectfully submit that the rejection of Claim 9 under the provisions of 35 U.S.C. §112, second paragraph, the Examiner contending that it is also unclear what is meant by "function of acquiring," and a 'function of determining a bone resection margin" is moot, in light of the current amendments to Claim 9 to recite, inter alia, "wherein the intraoperative assistance function includes: acquiring, from the database, the computer model data on the intra-medullary rod to be inserted; reading the computer model data, acquired from the database, on the intra-medullary rod to be inserted; acquiring, by a C-arm fluoroscopic apparatus, radiographic image data of the intra-medullary rod inserted into a tibia of the patient; acquiring, on the radiographic image data obtained by the fluoroscopic apparatus,

rotational position information of the intra-medullary rod in a medullary cavity of the patient based on the position of the intersection of the pair of wires of the intra-medullary rod; and determining a resected bone surface using the intra-medullary rod as a reference anatomical axis."

Applicants respectfully submit that all of the Claims presented for consideration by the Examiner patentably distinguish over the teachings of the references applied by the Examiner in rejecting Claims in the Office Action mailed October 8, 2010, that is, the teachings of the U.S. Patent No. 6,205,411 to DiGioia, III et al. (hereinafter DiGioia), U.S. Patent No. 5,108,398 to McQueen et al. (hereinafter McQueen) and U.S. Patent No. 5,275,603 to Ferrante et al. (hereinafter Ferrante) under the provisions of 35 U.S.C. §103(a).

The present invention is directed to a total knee joint replacing operation assisting terminal. As described within Applicants' Specification, the present inventors, in studying surgical treatments of lower limbs have found one surgical treatment of the knee is a total knee arthroplasty (hereinafter 'TKA') in which the entire articular surface is resected and is filled with artificial femoral component, tibial component, and tibia insert. Specification, page 1, line 25 through page 2, line 3. Applicants have found that in a TKA, a patient's knee area is incised, the tibia is resected, and a total knee joint component (implant) having a synthetic resin member, for replacing the joint, is mounted on the incisal surface of the tibia. Specification, page 2, lines 3-7.

Applicants have found that a conventional TKA setting position evaluatiuon is generally performed by examining X-ray images of two directions, front and lateral. Specification, page 2, line 11-13. Applicants have noted that 2-dimentional evaluations create difficulties in regulating the front of the knee during X-ray

scanning, if the knee is deformed or under a bending contracture, which in-turn affects the evaluation of the setting position. Specification, page 2, line 13-15.

Applicant have noted a known operation using a planning stage prior to intervention, wherein a transparent template and setting position plan are established using a X-ray image of a patient's knee and the size of a total knee corresponding to the shape of an individual patient. Specification, page 2, line 25 through page 3, line 4. Applicants have noted that during this operation, a rod is inserted into the bone marrow of the patient, and a bone cutting jig is connected to the rod in the direction of the setting position. Specification, page 3, lines 4-7. Applicants noted that the jig allows a surgeon to cut the bone according to the plan. Specification, page 3, line 7-8. Applicants noted that this jig is often a modular apparatus installed at the front end of a femur and introduced into a bore in the direction of an anatomical axis. Specification, page 3, lines 10-13.

Applicants have noted that conventional technologies related to TKA only allowed estimation of the resected bone surface with a rod in the abduction and adduction directions. Specification, page 3, lines 15-20. Applicants also noted that since the estimation was not possible in the rotation and bending directions, a bone cutting device corresponding to each had to be attached and each direction was determined by observation with the naked eye. Specification, page 3, lines 20-23. Applicants noted that this method poses difficulties when determining a precise direction of the resected bone surface, and the method required bulky surgical instruments. Specification, page 3, line 25 through page 4, line 1.

Against this background, Applicants provide a total knee joint replacing operation assisting terminal, constituted by a computer configured to assist a total knee joint replacing operation by performing a planning assistance function and an

intraoperative assistance function, so that the foregoing problems may be avoided. Specifically, Applicants have found that when the planning assistance function is used before an intervention on a patient, and the intraoperative assistance function is used during the intervention on a patient, whereby the terminal is configured to assist the total knee joint replacing operation performed with aid of a bone cutting positioning jig indicating a bone cutting direction by the intraoperative assistance function; wherein the bone cutting positioning jig comprises a bone cutting direction indicator having a base, a universal joint being movably and rotatably supported around three axes to the base of the bone cutting direction indicator through a ball joint and having a direction indicating jig, and an intra-medullary rod fixed to one end of the universal joint; wherein the intra-medullary rod comprises, a cylindrical body made of an X-ray transmitting material fixed at a central portion between a pair of both ends of the intra-medullary rod, a plurality of wires, which are made of a material that does not transmit X-ray and are deposited at regular intervals along a surface of the cylindrical body in the circumferential direction, being extended in an axial direction in a spiral shape; wherein an intersection of each of the wires having a marker indicator function providing rotational position information; wherein each of the wires is made in a way that a starting end and a terminating end of the cylindrical body are connected by the shortest distance along the outer surface thereof; wherein the planning assistance function includes: acquiring a load shaft of a patient's foot from 3-dimensional radiographic image data, and storing computer model data, on the intra-medullary rod to be inserted into a medullary cavity, in a database; wherein the intraoperative assistance function includes: acquiring, from the database, the computer model data on the intra-medullary rod to be inserted; reading the computer model data, acquired from the database, on the intra-medullary rod to be inserted;

acquiring, by a C-arm fluoroscopic apparatus, radiographic image data of the intra-medullary rod inserted into a tibia of the patient; acquiring, on the radiographic image data obtained by the fluoroscopic apparatus, rotational position information of the intra-medullary rod in a medullary cavity of the patient based on the position of the intersection of the pair of wires of the intra-medullary rod; and determining a resected bone surface using the intra-medullary rod as a reference anatomical axis; and wherein an anterior articular surface of the femur is determined perpendicularly to the load shaft of the patient from an angle with the femoral load shaft determined using the planning assistance function before the intervention, and a bone surface to be resected is determined, the above noted problems may be avoided.

Specifically, Applicants have developed a total knee joint replacing operation assisting terminal, constituted by a computer configured to assist a total knee joint replacing operation by performing a planning assistance function and an intraoperative assistance function, wherein data on a femoral model, a rod on the drawing and 3-dimensional model of a total component (implant) are acquired from the database of the total knee joint replacing operation assisting terminal. Specification, page 28, lines 15-18. Image data of a tibia, which is the bone cutting target of a patient, may be obtained by C-arm radiographic apparatus and a CT scanner. Specification, page 16, lines 3-4; and page 28, lines 20-21. The radiographic image data and the CT image data are read by a computer, thereby 3-dimensionalizing the bone shape. Specification, page 28, lines 23-24. From the 3-dimensional radiographic image data thus acquired, a load shaft of the patient's foot is determined. Specification, page 16, lines 7-8. In addition, based on the respective 3-dimensional data of the acquired radiographic image data and the

data of the implant's shape to be mounted, a 3-dimensional simulation for mounting the implant is performed. Specification, page 16, lines 9-12. The 3-dimensional data and the data on the total knee joint mount position obtained from the 3-dimensional simulation are recorded and kept in the database. Specification, page 16, lines 12-15.

According to the present invention, it becomes possible to accurately recognize the direction of a rod from a narrow field of vision for fluoroscopy, by using the special bone cutting positioning jig employing the intra-medullary rod. Specification, page 10, lines 16-19. The coordinate system (exclusive of rotation) of the intra-medullary rod is determined by digitizing, with help of the intra-medullary rod of the present invention, both ends of the intra-medullary rod with the radiographic image data during the operation. Specification, page 9, line 9 through page 10, line 24. Next, by digitizing the intersection of steel wires buried in the cylindrical body made of a X-ray transmitting material of the intra-medullary rod, a distance from the reference position in the axial direction is obtained, and a rotational angle of the intra-medullary rod corresponding to this distance can be measured. Specification, page 10, line 24 through page 11, line 4.

In the intraoperative assistance function, the intra-medullary rod is inserted into a lesion of a patient during the operation, and two-directional X-ray fluoroscopic images are taken using the C-arm fluoroscopic apparatus, thereby 3-dimensionalizing the bone shape. Specification, page 10, lines 4-7. The position alignment is performed based on the plan before the intervention, and a resected bone surface about the direction of the intra-medullary rod is calculated based on the total joint setting position. Specification, page 10, lines 7-11. Meanwhile, a bone cutting jig is connected to the intra-medullary rod via the universal joint, and

using the bone cutting direction indicator, the direction of the bone cutting jig is determined to coincide with the resected bone surface obtained from the calculation. Specification, page 10, lines 11-15.

Therefore, Applicants provide a total knee joint replacing operation assisting terminal wherein a computer model of the intra-medullary rod to be inserted during an operation is called and is superposed on an image photographed during the operation, whereby the relative positions of the intra-medullary rod and bone during the operation and the relative positions of the intra-medullary rod and bone of the planning before the intervention are computed, respectively. Specification, page 32, lines 14-20.

In response to the rejection of Claim 9 under 35 U.S.C. §103(a) as being unpatentable over DiGioia in view of McQueen and Ferrante, Applicants respectfully submit that the combined teachings of DiGioia, McQueen and Ferrante would not have disclosed or rendered obvious the recitations of Claim 9, for the reasons noted below.

DiGioia would have disclosed an apparatus for facilitating the implantation of an artificial component in one of a hip joint, a knee joint, a hand and wrist joint, an elbow joint, a shoulder joint, and a foot and ankle joint. DiGioia, abstract. DiGioia would have disclosed a pre-operative geometric planner, pre-operative kinematic biomechanical simulator, and intra-operative navigational software are implemented using a computer system. DiGioia, col 6, lines 9-12. DiGioia would have disclosed that during the intra-operative stages of the method, the computer system is used to display the relative locations of the objects being tracked with a tracking device. DiGioia, col. 6, lines 24-26. DiGioia would have disclosed that the tracking device can employ any type of tracking method as may be known in the art, for example,

emitter/detector systems including optic, acoustic or other wave forms, shape based recognition tracking algorithms, or video-based, mechanical, electromagnetic and radio frequency (RF) systems. DiGioia, col. 6, lines 30-35.

DiGioia would have disclosed that the skeletal structure of the joint is determined using tomographic data (three dimensional) or computed tomographic data (pseudo three dimensional data produced from a series of two dimensional scans) or other techniques from the skeletal data source. DiGioia, col. 6, lines 49-54. DiGioia would have disclosed that a pre-operative procedure is performed, so that the artificial components can be properly sized and implant positions can be properly determined. DiGioia, col. 7, lines 64-67. DiGioia would have disclosed that geometric models of the joint and the artificial components are used to perform biomechanical simulations of the movement of the joint containing the implanted artificial components. DiGioia, col. 7, lines 19-22.

DiGioia would have also disclosed 3D surface registration, wherein discrete registration points are obtained from the joint skeletal structure to define the intra-operative position of the patient's joint. DiGioia, col. 8, lines 17-19. DiGioia would have disclosed that the registration points are fitted to the joint model of the skeletal structure to determine a coordinate transformation that is used to align the joint model with the intra-operative position of the patient's joint. DiGioia, col. 8, lines 19-24.

However, Applicants respectfully note the statements on page 4 of the Office Action mailed October 10, 2010, that DiGioia does not disclose a bone cutting positioning jig or an intra-medullary rod.

Ferrante would have disclosed a rotationally and angularly adjustable tibial cutting guide and method of use. Ferrante, title. Ferrante would have disclosed that

an adjustment means includes a ball plunger assembly extending from anterior surface of a guide block mating with indents formed in a flange of the guide means. Ferrante, col. 3, lines 44-47. Ferrante would have also disclosed that as a ball plunger assembly engages indents, the guide means is releasably locked in one of the five angular positions, and the indents act to prevent movement of the guide means, unless a certain excess force is applied to overcome the pressure exerted between ball plunger assembly against the indents. Ferrante, col. 3, lines 47-53. Ferrante would have disclosed that the angular movement of the guide means varies between 0° and 22° taking into account a medial or lateral resection of tibia, i.e., the indents represent angles of -22°, -12°, 0, 12°, and 22°, respectively. Ferrante, col. 3, lines 53-57.

Ferrante would have disclosed the angular alignment of the tibial cutting guide is adjusted by pivoting the guide means until ball plunger assembly engages one of the five indents. Ferrante, col. 5, lines 18-21. Ferrante would have disclosed that once the correct angular alignment is selected, a threaded screw is tightened against the surface to lock the guide means at the desired angle, and the surgeon may resect a wedge section from the medial or lateral surface of the tibia. Ferrante, col. 5, lines 21-26. Ferrante would have disclosed that after angular alignment, the proper degree of rotational alignment of tibial trial base about the longitudinal axis of tibia is retained by inserting at least one alignment pin through alignment holes and into the surface. Ferrante, col. 5, lines 27-31. Ferrante would have disclosed that an alignment pin is inserted opposite the surface to be resected, so that the pin does not interfere with the cutting tool. Ferrante, col. 5, lines 31-33.

McQueen would have disclosed an orthpaedic knee fusion apparatus. McQueen, title. McQueen would have disclosed an orthopaedic surgical implant

apparatus that includes an elongated intramedullary rod assembly for use in uniting a pair of bone segments wherein each of the bone segments includes a medullary cavity. McQueen, abstract. McQueen would have disclosed an objective of the disclosed invention of providing an orthopaedic implant apparatus suitable for bone fracture healing and stabilization or fusion of joints. McQueen, col. 2, lines 39-41.

McQueen would have also disclosed an object of the disclosed invention of providing an implant apparatus and accompanying surgical instrumentation which allows the device to be implanted without requiring the use of X-ray techniques which are time consuming and present dangers to those exposed to the X-rays. McQueen, col. 2, lines 48-53.

McQueen would have disclosed an intramedullary rod assembly 10 manufactured from material that is biocompatible with human tissue and that can provide sufficient mechanical strength to support the fused bone segments. McQueen, col. 5, lines 10-14. McQueen would have disclosed that the material may either be metallic or non-metallic, and preferably cast, forged, or rolled in cobalt-chromium, titanium, or other high strength stainless steel. McQueen, col. 5, lines 14-17.

McQueen would have disclosed an installation assembly to assist installation of the intramedullary rod includes a femoral base alignment assembly and a tibial base alignment assembly. McQueen, col. 5, lines 22-25. McQueen would have disclosed that the femoral base alignment assembly includes a femoral instrumentation bracket, an instrumentation plug, and an adjustment bolt. McQueen, col. 5, lines 22-25. McQueen would have disclosed that the instrumentation plug is a hollow cylindrical member that includes a threaded inner surface and an outer surface that is provided with a threaded portion adjacent a proximal end thereof.

McQueen, col. 5, lines 35-39. McQueen would have disclosed that the intramedullary rod assembly is constructed by first positioning the slider on the distal end of the femoral base and then fitting the femoral plug on the femoral base such that a friction fit is formed between the base and the plug. McQueen, col. 6, lines 13-17. McQueen would have disclosed that a femoral instrumentation bracket is arranged on the femoral base by first threading the adjustment bolt partially through the instrumentation plug and threading the instrumentation plug partially into the distal end of a slider. McQueen, col. 6, lines 32-36. McQueen would have disclosed that when the adjustment bolt is tightened against the femoral base, the slider, instrumentation plug and instrumentation bracket are retained against further axial or rotative movement relative to the femoral base. McQueen, col. 6, lines 50-54.

Applicants respectfully submit that a combination of DiGioia, Ferrante and McQueen would not have disclosed or rendered obvious the recitations of Claim 9, because DiGioia would not have disclosed or rendered obvious, at least, a bone cutting positioning jig or an intra-medullary rod, as noted above, and Ferrante and Mcqueen would not have remedied the deficiencies of DiGioia, for the reasons noted below.

Applicants respectfully traverse the characterization, as set forth on page 4 of the Office Action mailed October 8, 2010, of the "cutting positioning jig [which] comprises a bone cutting direction indicator having a base, a universal joint being movably and rotatably supported around three axes to the base of the bone cutting direction indicator through a ball joint and having a direction indicating jig, and an intra-medullary rod fixed to one end of the universal joint" as recited in Claim 9, as the ball plunger assembly that engages indents, as disclosed in Ferrante. Applicants respectfully submit that the ball plunger mating and engaging with indents along <u>one</u>

axis of a flange to be locked in one of the five angular positions, as described in Ferrante, and illustrated in Fig. 2 of Ferrante, would not have the same function or structure as a bone cutting and positioning jig that comprises a bone cutting direction indicator having a base, a universal joint being movably and rotatably supported around three axes to the base of the bone cutting direction indicator through a ball joint, as recited in Claim 9. Therefore, Applicants respectfully submit that Ferrante would not have remedied the deficiencies of DiGioia, at least, with respect to the bone cutting positioning jig recited in Claim 9.

Moreover, Ferrante would not have disclosed or rendered obvious, at least, "the intra-medullary rod comprises, a cylindrical body made of an X-ray transmitting material fixed at a central portion ..., a plurality of wires, which are made of a material that does not transmit X-ray and are deposited at regular intervals along a surface of the cylindrical body... in a spiral shape;... and the wires having a marker indicator function providing rotational position information;... based on the position of the intersection of the pair of wires of the intra-medullary rod," as recited in Claim 9, because Ferrante does not disclose an intra-medullary rod or rotational position information of the intra-medullary rod in a medullary cavity of the patient before and during an operation.

In addition, Applicants respectfully submit that McQueen would not have remedied the deficiencies of DiGioia and Ferrante, because McQueen would not have disclosed or rendered obvious, at least, the bone cutting positioning jig or the intra-medullary rod, as recited in Claim 9. Applicants respectfully traverse the characterization, on page 4 of the Office Action mailed October 8, 2010, of intra-medullary rod, as recited in Claim 9, as the intramedullary rod assembly and instrumentation plug that would have been disclosed by McQueen, because

McQueen would not have disclosed or rendered obvious the intra-medullary rod recited in Claim 9, which comprises, "a cylindrical body made of an X-ray transmitting material fixed at a central portion between a pair of both ends of the intra-medullary rod, a plurality of wires, which are made of a material that does not transmit X-ray and are deposited at regular intervals along a surface of the cylindrical body in the circumferential direction, being extended in an axial direction in a spiral shape," and "the intersection of each of the wires [have] a marker indicator function providing rotational position information," because the intramedullary rod assembly including the slider, femoral base, and femoral plug, configured with the adjustment bolt and instrumentation plug, of McQueen would not have provided rotational information before and during operation, would not have a marker indication function providing rotational information, and none of the parts that would have been disclosed by McQueen are made of an X-ray transmitting material. Applicants respectfully submit that the instrumentation plug of McQueen merely connects the adjustment bolt to the slider and none of the parts provide rotational position information. Therefore, Applicants respectfully submit that McQueen would not have remedied the deficiencies of DiGioia and Ferrante, which are noted above.

Therefore, for the reasons noted above, Applicants respectfully submit that a combination of DiGioia, Ferrante, and McQueen would not have disclosed or rendered obvious the recitations of Claim 9.

In addition, Applicants respectfully submit that DiGioia and McQueen are not properly combinable references, or there would have been no apparent reason to combine DiGioia and McQueen, because, as noted above, DiGioia would have disclosed that geometric models of the joint and the artificial components are used to perform biomechanical simulations of the movement of the joint containing the

implanted artificial components, while McQueen would have disclosed an orthpaedic knee fusion apparatus for uniting a pair of bone segments. Therefore, DiGioia would have disclosed a technology for promoting movement of joints, while McQueen would have disclosed a technology for fusing joints, which is the opposite of the purpose of DiGioia. Therefore, Applicants respectfully submit that that DiGioia and McQueen are not properly combinable and there would have been no apparent reason to combine the technologies of the two references, which are directed to opposite objectives.

Moreover, Applicants respectfully submit that McQueen would have taught away from the recitations of Claim 9, because McQueen would have disclosed a device to be implanted without requiring the use of X-ray techniques which are time consuming and present dangers to those exposed to the X-rays, as noted above, while Claim 9 recites an intra-medullary rod comprises a cylindrical body made of an X-ray transmitting material. Therefore, Applicants respectfully submit that McQueen would have taught away from the recitations of Claim 9.

Therefore, for the reasons noted above, Applicants respectfully submit that Claim 9 would not have been obvious over DiGioia in view of McQueen and Ferrante.

Applicants respectfully submit that Claims 10-16 would not have been obvious over DiGioia in view of McQueen and Ferrante, because Claims 10-16 depend on Claim 9, which would not have been obvious over DiGioia in view of McQueen and Ferrante, as noted above. A dependent claim refers back to and incorporates the recitations of the claim on which it depends. Moreover, the additional recitations of a dependent claim must be read as a whole with the recitations of the claim on which it depends. Therefore, applicants respectfully submit that Claims 10-16 would not

have been obvious over DiGioia in view of McQueen and Ferrante, and the additional recitations of Claims 10-16 would not have been obvious over DiGioia in view of McQueen and Ferrante.

In view of the foregoing comments and amendments, reconsideration and allowance of all claims presently in the application are respectfully requested.

To the extent necessary, Applicants petition for an extension of time under 37 CFR 1.136. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to the Deposit Account of Antonelli, Terry, Stout & Kraus, LLP, Deposit Account No. 01-2135 (Docket No. 520.46649X00) and please credit any excess fees to such Deposit Account.

Respectfully submitted,

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